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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	FINKELSTEIN, J. D., "The metabolism of homocysteine: pathways and regulation", Eur J Pediatr, 1998, pp. S40-S44, Vol. 157, No. 2.	
	2.	CHAO, Chia-Lun, et al., "The graded effect of hyperhomocysteinemia on the severity and extent of coronary atherosclerosis", Atherosclerosis, 1999, pp. 379-386, Vol. 147.	
	3.	SPENCE, J. David, et al., "Plasma homocyst(e)ine concentration, but not MTHFR genotype, is associated with variation in carotid plaque area", Stroke, 1999, pp. 969-973, Vol. 30.	
	4.	VASAN, Ramachandran S., et al., "Plasma homocysteine and risk for congestive heart failure in adults without prior myocardial infarction", JAMA, 2003, pp. 1251-1257, Vol. 289, No. 10.	
	5.	UBBINK, Johan B., et al., "Vitamin requirements for the treatment of hyperhomocysteinemia in humans" Human and Clinical Nutrition, 1994, pp. 1927-1933, Vol. 124.	
	6.	HACKAM, Daniel, G., et al., "What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 µmol/L", American Journal of Hypertension, 2000, pp. 105-110, Vol. 13, No. 1.	
	7.	ANWAR, Wafaa, et al., "Hyperhomocysteinemia is related to residual glomerular filtration and folate, but not to methyltetrahydrofolate-reductase and methionine synthase polymorphisms, in supplemented end-stage renal disease patients undergoing hemodialysis", Clin Chem Lab Med, 2001, pp. 747-752, Vol. 39, No. 8.	
	8.	ARNADOTTIR, M., et al., "The effect of reduced glomerular filtration rate on plasma total homocysteine concentration", Scand J Clin Lab Invest, 1996, pp. 41-46, Vol. 56.	
	9.	HOUSE, Andrew, et al., "Effect of multivitamins on plasma homocysteine levels in patients on hemodialysis", ASAIO Journal, 1999, pp. 94-97, Vol. 45.	
	10.	SPENCE, J. David, et al., "Effect of usual doses of folate supplementation on elevated plasma homocyst(e)ine in hemodialysis patients: no difference between 1 and 5 mg daily", Am J Nephrol, 1999, pp. 405-410, Vol. 19.	
	11.	ELIAN, Kelly M., et al., "Hydroxocobalamin reduces hyperhomocysteinemia in end-stage renal disease", Metabolism, 2002, pp. 881-886, Vol. 51, No. 7.	
	12.	BOSTOM, Andrew G., et al., "Short term betaine therapy fails to lower elevated fasting total plasma homocysteine concentrations in hemodialysis patients maintained on chronic folic acid supplementation", Atherosclerosis, 1995, pp. 129-132, Vol. 113.	
	13.	HOUSE, Andrew, et al., "Randomized trial of high-flux vs low-flux haemodialysis: effects on homocysteine and lipids", Nephrology Dialysis Transplantation, 2000, pp. 1029-1034, Vol. 15.	
	14.	VRIESE, An S., et al., "Effect of dialyser membrane pore size on plasma homocysteine levels in haemodialysis patients", Nephrology Dialysis Transplantation, 2003, pp. 2596-2600, Vol. 18.	

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Sheet 2 of 3

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 Art Unit N/A
 Examiner Name N/A
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	15.	FRIEDMAN, Alon N., et al., "The effect of N-acetylcysteine on plasma total homocysteine levels in hemodialysis: a randomized, controlled study", American Journal of Kidney Diseases, 2003, pp. 442-446, Vol. 41, No. 2.	
	16.	VENTURA, Paolo, et al., "Urinary and plasma homocysteine and cysteine levels during prolonged oral N-acetylcysteine therapy", Pharmacology, 2003, pp. 106-114, Vol. 68.	
	17.	LAUTERBURG, Bernhard, et al., "Depletion of total cysteine, glutathione, and homocysteine in plasma by ifosfamide/mesna therapy", Cancer Chemother Pharmacol, 1994, pp. 132-136, Vol. 35.	
	18.	PENDYALA, Lakshmi, et al., "Intravenous ifosfamide/mesna is associated with depletion of plasma thiols without depletion of leukocyte glutathione", Roswell Park Cancer Institute, 2000, pp.1314-1321, Vol. 6.	
	19.	PENDYALA, Lakshmi, et al., "Modulation of plasma thiols and mixed disulfides by BNPT787 in patients receiving paclitaxel/cisplatin therapy", Cancer Chemother Pharmacol, 2003, pp. 376-384, Vol. 51.	
	20.	JACOBSEN, Donald W., et al., "Rapid HPLC determination of total homocysteine and other thiols in serum and plasma: sex differences and correlation with cobalamin and folate concentrations in healthy subjects", Clin. Chem., 1994, pp. 873-881, Vol. 40, No. 6.	
	21.	BOSTOM, Andrew G., et al., "Hyperhomocysteinemia and traditional cardiovascular disease risk factors in end-stage renal disease patients on dialysis: a case-control study", Atherosclerosis, 1995, pp. 93-103, Vol. 114.	
	22.	BOSTOM, Andrew G., "Homocysteine: 'expensive creatine' or important, modifiable risk factor for arteriosclerotic outcomes in renal transplant recipients?", J Am Soc of Nephrol, 2000, pp. 149-151, Vol. 11.	
	23.	DUCLOUX, Didier, et al., "Hyperhomocysteinemia therapy in haemodialysis patients: folic versus folic acid combination with vitamin B6 and B12", Nephrol Dial Transplant, 2002, pp. 865-870, Vol. 17.	
	24.	SIGIT, Joseph I., et al., "Total plasma homocysteine and related amino acids in end-stage renal disease (ESRD) patients measured by gas chromatography-mass spectrometry - comparison with the Abbott IMx homocysteine assay and the HPLC method", Clin Chem Lab Med, 2001, pp. 881-890, Vol. 39, No. 8.	
	25.	SORIA, C., et al., "Concentrations of total homocysteine in plasma in chronic renal failure", Clinical Chemistry, 1990, pp.2137-2138, Vol. 38, No. 12.	
	26.	SQUID, Abdul-Kader, et al., "Blood thiols following amifostine and mesna infusions, a pediatric oncology group study", The American Society for Pharmacology and Experimental Therapeutics, 2001, pp. 1460-1468, Vol. 29.	
	27.	YAMAMOTO, Nobuko, et al., "Effect of cysteine on expression of cystathionine β -synthase in the rat liver", J. Nutr. Sci. Vitaminol., 1995, pp. 197-205, Vol. 41.	
	28.	GOREN, Marshall P., et al., "Reduction of dimesna to mesna by the isolated perfused rat liver", Cancer Research, 1998, pp. 4358-4362, Vol. 58.	

Examiner Signature	Date Considered
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